APPENDIX A

NOT RECOMMENDED FOR FULL-TEXT PUBLICATION

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

Case No. 07-4465

[Filed August 28, 2008]

CARETOLIVE,	)
	)
Plaintiff-Appellant,	)
	)
v.	)
	)
ANDREW VON ESCHENBACH, Commissioner, Food and Drug Administration, et al.,	)
	)
Defendants-Appellees.	)
	)

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO

BEFORE: BATCHELDER and GILMAN, Circuit Judges; ZOUHARY[1], District Judge.

ALICE M. BATCHELDER, Circuit Judge. Plaintiff–Appellant CareToLive ("CTL"), appeals the judgment of the district court dismissing CTL's action for lack of subject matter jurisdiction. CTL, which characterizes itself as an association of cancer patients, patient families, doctors, investors, and advocates, filed suit in the district court to challenge the Food and Drug Administration's ("FDA") decision not to immediately approve a Biologics License Application ("BLA") for the vaccine Provenge. The FDA neither approved nor denied the application, but instead issued a Complete Response Letter to the vaccine's sponsor, Dendreon Corp., requesting more information. CTL's lawsuit named as defendants the Commissioner ofthe FDA, Andrew von Eschenbach, M.D., and the Secretary of the United States Department of Health and Human Services, Michael Leavitt, in their official capacities; the complaint also named two FDA officials, Richard Pazdur, M.D., and Howard Scher, M.D., in both their official and individual capacities.

On November 21, 2007, the district court dismissed CTL's official-capacity claims for lack of subject matter jurisdiction, citing ripeness, finality, and sovereign immunity. CTL filed an immediate notice of appeal. On December 4, 2007, the district court dismissed CTL's individual-capacity claims. CTL filed no notice

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[1] The Honorable Jack Zouhary, U.S. District Judge for the Northern District of Ohio, sitting by designation.

of appeal from the latter order, and appeals only the dismissal of its official-capacity claims.

After carefully reviewing the record, the applicable law, the parties' briefs and counsels' arguments, we conclude that the district court did not err in its conclusion that it lacked subject matter jurisdiction because, at the very least, CTL's action is unripe. As the district court's opinion carefully and correctly sets out the law governing the issues raised, and clearly articulates the reasons underlying its decision, issuance of a full written opinion by this court would serve no useful purpose. Accordingly, for the reasons stated in the district court's opinion dismissing CTL's official-capacity claims, we **AFFIRM**.

APPENDIX B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

Case No. 2:07-cv-729

[Filed November 21, 2007]

CARETOLIVE,	)
	)
Plaintiff,	)
	)
v.	)
	)
ANDREW von ESCHENBACH, et al.,	)
	)
Defendants.	)
	)

JUDGE GREGORY L. FROST
Magistrate Judge Norah McCann King

OPINION AND ORDER

This action involves a biologics license application ("BLA") that was submitted to the Food and Drug Administration ("FDA") for Provenge, a biological product which is intended to treat a particular type of metastatic prostate cancer and is manufactured by Dendreon Corporation. Plaintiff CareToLive

challenges the decision of the FDA "not to approve Provenge for immediate use and instead [to] issue[] a Complete Response Letter requesting more data." (Doc. # 22.) This matter is before the Court on Defendants' Motion to Dismiss Plaintiff's Official Capacity Claims (Doc. # 38) and on Defendants' Motion to Strike Improper Supplemental Memorandum (Doc. # 59). For the reasons that follow, the Court **GRANTS** both of Defendants' motions.

I. BACKGROUND

A. The Parties

Plaintiff characterizes itself as an association of "cancer patients, patient families, doctors, investors, and advocates." (Doc. # 22 at 2.) Plaintiff brought this action against the Commissioner of the FDA Andrew von Eschenbach, M.D., and the Secretary of the United States Department of Health and Human Services Michael Leavitt, in their official capacities and against Richard Pazdur, M.D. and Howard Scher, M.D., in both their official and individual capacities.[1] *Id.* ¶¶ 4, 5, 6, 7. Pazdur is the Director of the Office of Oncologic Drug Products in the FDA's Center for Drug Evaluation and Research. *Id.* ¶ 6. Scher is a special government employee who served on the FDA Advisory Committee that considered the Provenge BLA. *Id.* ¶ 7.

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[1] Defendants filed a separate motion to dismiss the claims against Pazdur and Scher (Doc. # 37). The Court addresses arguments for dismissal of the personal capacity claims set forth in that motion by separate Opinion and Order.

B. Statutory and Regulatory Scheme

Biological products are defined under the Public Health Service Act ("PHSA") as any "virus, therapeutic serum, toxin, antitoxin, vaccine . . . or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i). Biological products can also be drugs, and are generally subject to the same statutory and regulatory requirements that apply to drugs. *See* 42 U.S.C. § 262(j) (the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 321, applies to biological products subject to regulation under the PHSA, 42 U.S.C. § 262).

The FDCA defines "drug" to include, *inter alia*, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man . . . ." 21 U.S.C. § 321(g)(1)(B). A "new drug" is defined as either (1) a drug that is "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof," or (2) a drug that, "as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions." 21 U.S.C. § 321(p).

1. Biological Product Approval Process

For unapproved biological products, the sponsor seeks FDA approval by submitting a BLA pursuant to the PHSA. 42 U.S.C. § 262(a). The FDA will approve a BLA for an unapproved biological product if the BLA demonstrates that the product is safe, pure, and potent, *id.* § 262(a)(2)(C)(i)(I), and that the facility in which the product is manufactured "meets standards designed to assure that the biological product continues to be safe, pure, and potent," *id.* § 262(a)(2)(C)(i)(II).

Generally, when the sponsor of a biological product has completed the clinical trial process, it can submit a BLA in accordance with 21 C.F.R. § 601.2(a). The required documentation in a BLA provides information for the FDA evaluation of the biological product, including the results of clinical trials, the composition of the drug, manufacturing information, and sample labeling. *Id.* The FDA will not consider a BLA to be filed until all pertinent data have been received by the agency. *See id.*

2. FDA Responses to a BLA

In response to a BLA, the FDA may refuse to file it if it is incomplete. *See* FDA, "*Refusal to File Procedure for Biologics License Applications*," SOPP 8404, available at http://www.fda.gov/cber/regsopp/8404.htm. Further, under certain circumstances the FDA will approve a BLA, 21 C.F.R. § 601.4(a), or deny it and provide the applicant the opportunity for a hearing, *id.* § 601.4(b). Finally, if there are deficiencies in the BLA, the FDA may send a Complete

Response Letter declining to approve the BLA as it was presented and requesting additional information from the sponsor. *Applications for Approval to Market a New Drug*, 69 Fed. Reg. 43351, 43352 (July 20, 2004) (to be codified at 21 C.F.R. §§ 314.110, 314.120).

C. Statement of Facts

Provenge is a biological product intended to treat a particular type of metastatic prostate cancer. (Doc. # 22 ¶ 15.) Provenge uses a patient's own cells to prepare a final product designed for infusion back into the patient's bloodstream to activate his or her immune system against the cancer cells. *Id.* ¶¶ 14, 16. Provenge is referred to as an active cellular immunotherapy, designed to elicit a patient's specific immune response to a target antigen expressed in prostate cancer tissue, *i.e.*, to train a patient's immune system to recognize cancer cells and to fight them. *Id.* ¶¶ 14-16, 19. Because it is designed to act in this manner, Provenge is a vaccine and thus a "biological product" subject to FDA regulation under the PHSA. 42 U.S.C. § 262(i).

Dendreon has been studying Provenge's safety and effectiveness in clinical trials pursuant to an investigational new drug application it submitted to the FDA in 1996. *See* Transcript of March 29, 2007 Cellular, Tissue, and Gene Therapies Advisory Committee Meeting at 20; (Doc. # 23, Ex. C.) Dendreon submitted its BLA for Provenge in late 2006, and the FDA considered it to be filed in January 2007. (Doc. # 22 ¶ 27.) Because Provenge is an immunotherapy vaccine, regulatory responsibility for reviewing and, ultimately, approving or denying

approval of the BLA rests with the Office of Cellular, Tissue, and Gene Therapies in the FDA Center for Biologics Research and Evaluation ("CBER"). *Id.* ¶ 29; 68 Fed. Reg. 38067, 38068 (June 26, 2003).

In the Amended Complaint, Plaintiff claims that Pazdur intentionally violated "Federal Regulations and US Law by improperly controlling the makeup of the FDA [Office of Cellular, Tissue, and Gene Therapies] Advisory Committee, and applying improper pressure on Committee members" in an effort to deny due process for the BLA for Provenge; purposely placed on the Advisory Committee two oncologists who had conflicts of interest and who Pazdur was sure would be opposed to the approval of Provenge; prior to the vote, changed the question posed to the Advisory Committee members to get them to recommend against approval of Provenge; and "recruited and illegally used [the] FDA employees" at and after the Advisory Committee meeting to assist Pazdur in "wrecking" the Provenge BLA by requesting anti-Provenge letters and "design[ing] a method for 'leaking' them to the press." (Doc. # 22 ¶¶ 6, 50, 62, 63, 67, 70, 71, 72, 73, 77, 79.)

Further, Plaintiff alleges that Scher "fail[ed] to disclose conflicts of interest that would have placed the FDA on notice that his own personal interests provided him additional reasons" to be opposed to the immediate approval of the Provenge BLA; wrote a letter attacking Provenge that contained false information and that was later "leaked to the press"; and failed to exercise care in the responsibility he undertook to aid patients. *Id.* ¶¶ 7, 60, 70, 72, 77, 79.

Plaintiff also alleges Leavitt, who controls that agency with FDA oversight duties, "ignored and continues to ignore the agency's dysfunction." *Id.* ¶ 5. Finally, Plaintiff claims that von Eschenbach "decided not to approve Provenge for immediate use and instead issued a Complete Response Letter requesting more data which might not be available until 2010." *Id.* ¶ 43.

On May 8, 2007, CBER issued a Complete Response Letter to Dendreon, Provenge's sponsor, declining to approve the BLA in its current form because of various deficiencies. *See* Dendreon Corp., "*Dendreon Receives Complete Response Letter from FDA for Provenge Biologics License Application*," May 9, 2007, available at http://investor.dendreon.com/ReleaseDetail.cfm?ReleaseID=241649&Header=News ("*Dendreon Receives Complete Response Letter*"). The FDA requested that Dendreon submit additional information with respect to the chemistry, manufacturing, and controls section of the BLA, *id.*; such information is required to demonstrate that the facility in which the product would be manufactured "meets standards designed to assure that the biological product continues to be safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(II). The FDA also requested that Dendreon submit additional clinical data in support of its effectiveness claim. *Dendreon Receives Complete Response Letter*. Dendreon has since met with the FDA to discuss the additional data required to support licensure and indicated that it intends to proceed with its new Phase 3 study designed to measure survival and to submit such data to the FDA when it becomes available. *See* Dendreon Corp., "*Dendreon Announces FDA Confirms Data Required*

for Provenge Licensure," May 31, 2007, available at http://investor.dendreon.com/ReleaseDetail.cfm?ReleaseID=246500 &Header=News.

Plaintiff submitted a citizen petition to the FDA dated July 26, 2007. (Doc. # 2 Ex. B.) The FDA's Docket Branch received the citizen petition on July 27, 2007 and assigned it docket number 2007P-0297. *Id.* Under FDA regulations, a citizen petition is the mechanism for formally asking the agency to take a particular action, and is a prerequisite to filing suit on the subject. *See* 21 C.F.R. §§ 10.25, 10.30, 10.45. In its citizen petition, Plaintiff urges the Commissioner of Food and Drugs to "reverse [the FDA's] decision to deny immediate approval to Provenge." (Doc. # 2 Ex. B.) FDA regulations require the Commissioner, within 180 days of receipt of a citizen petition, to either approve the petition, deny the petition, or, if more time is required, issue a tentative response. 21 C.F.R. § 10.30(e)(2). On July 30, 2007, the FDA acknowledged receipt of the citizen petition, but otherwise has not yet responded. *See* 7/30/07 Letter., Jaffe to Kearney, available at http://www.fda.gov/ohrms/dockets/dockets/07p0297/07p-0297-ack0001-vol1.pdf.

On July 30, 2007, Plaintiff filed this action and on September 5, 2007, Plaintiff filed an amended complaint (Doc. # 22).

On October 5, 2007, Defendants Pazdur and Scher filed their motion to dismiss (Doc. # 37) and on October 24, 2007, Plaintiff filed its memorandum in opposition to that motion (Doc. # 46). Defendants filed their reply

in support of their motion to dismiss on October 31, 2007. (Doc. # 51.)

On October 5, 2007, Defendants filed their motion to dismiss the claims brought against them in their official capacity. (Doc. # 38.) On October 19, 2007, Plaintiff filed its memorandum in opposition to Defendants' motion (Doc. # 43) and on October 26, 2007, Defendants filed their reply in support of their motion.

On November 11, 2007, Plaintiff filed Plaintiff's Supplemental Memorandum in Support of Memorandum in Opposition to Defendant's Motion to Dismiss and as Supplement to Motion for Injunctive Relief. (Doc. # 58.) Defendants filed a motion to strike the supplemental memorandum on November 13, 2007. (Doc. # 59.)

II. MOTION TO STRIKE

Plaintiff filed a supplemental memorandum in support of its memorandum in opposition to Defendants' motions to dismiss. (Doc. #58.) Plaintiff contends that it has new evidence that this Court should view in its consideration of Defendants' motions to dismiss.

Defendants move to strike Plaintiff's supplemental memorandum pursuant to Rule 7.2 of the Southern District of Ohio Civil Rules, which allows the party opposing a motion to file an opposition brief; and the party filing a motion to support it with an opening brief and a reply brief. S.D. Ohio Civ. R. 7.2(a)(2). "No additional memoranda beyond those enumerated will

be permitted except upon leave of court for good cause shown." *Id.* Plaintiff has neither requested leave of Court to file its supplemental memorandum nor has it shown the good cause necessary to comply with Rule 7.2. Moreover, Plaintiff failed to consult with Defendants or to bring its allegedly new evidence to the attention of the Court, both as required by subsection (d) of Local Rule 7.2.

Consequently, the Court **GRANTS** Defendants' Motion to Strike Improper Supplemental Memorandum. (Doc. # 59.) However, the Court notes that there is nothing in Plaintiff's supplemental memorandum that would have changed this Court's analysis of Defendants' motions to dismiss.

III. STANDARD FOR MOTION TO DISMISS

Defendants move to dismiss under, *inter alia*, Rule12(b)(1) of the Federal Rules of Civil Procedure, which provides for dismissal for "lack of subject matter jurisdiction[.] Fed. R. Civ. P. 12(b)(1). "A Rule 12(b)(1) motion can either attack the claim of jurisdiction on its face, in which case all allegations of the plaintiff must be considered as true, or it can attack the factual basis for jurisdiction, in which case the trial court must weigh the evidence and the plaintiff bears the burden of proving that jurisdiction exists." *DLX, Inc. v. Kentucky*, 381 F.3d 511, 516 (6th Cir. 2004) (citing *RMI Titanium Co. v. Westinghouse Elec. Corp.*, 78 F.3d 1125, 1133-35 (6th Cir. 1996)). In this action, all parties have submitted evidence in support of their positions on dismissal and all parties point to disputed facts that they have called upon the Court to resolve. (Doc. ## 37, 38, 43, 46, 47, 51.) Thus, Defendants

mount a factual attack on the jurisdiction of this Court. The United States Court of Appeals for the Sixth Circuit instructs that,

> when a court reviews a complaint under a factual attack, as here, no presumptive truthfulness applies to the factual allegations. Such a factual attack on subject matter jurisdiction commonly has been referred to as a "speaking motion." *See generally* C. Wright & A. Miller, Federal Practice and Procedure § 1364, at 662-64 (West 1969). When facts presented to the district court give rise to a factual controversy, the district court must therefore weigh the conflicting evidence to arrive at the factual predicate that subject matter jurisdiction exists or does not exist. In reviewing these speaking motions, a trial court has wide discretion to allow affidavits, documents and even a limited evidentiary hearing to resolve disputed jurisdictional facts. (citations omitted.)

Ohio Nat'l Life Ins. Co. v. United States, 922 F.2d 320, 325 (6th Cir. 1990); *see also Nat'l Assoc. of Minority Contractors v. Martinez*, 248 F. Supp.2d 679, 681 (S.D. Ohio 2002) (applying foregoing standard).

IV. MOTION TO DISMISS OFFICIAL CAPACITY CLAIMS

Plaintiff claims that Defendants von Eschenbach, Leavitt, Pazdur, and Scher in their official capacities violated his rights under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 702, 704. In an official

capacity lawsuit, the official's employing agency is the real party in interest, and the suit "is, in all respects other than name, to be treated as a suit against the entity" that employs him. *Kentucky v. Graham*, 473 U.S. 159, 166 (1985). Though an official is named as a defendant, an official capacity suit "is not a suit against the official but rather is a suit against the official's office." *Will v. Mich. Dep't of State Police*, 491 U.S. 58, 71 (1989). Plaintiff's official capacity claims are accordingly analyzed as brought against the United States.

In their motion to dismiss, Defendants argue that this Court lacks subject matter jurisdiction over this action based on the doctrines of ripeness, finality, and sovereign immunity. This Court agrees.

A. Ripeness

"The ripeness doctrine 'is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction.' " *Airline Prof'l Ass'n of the Int'l Bhd. of Teamsters, Local Union No. 1224, AFL-CIO v. Airborne, Inc.*, 332 F.3d 983, 987 (6th Cir. 2003) (quoting *Reno v. Catholic Soc. Servs., Inc.*, 509 U.S. 43, 57 n.18 (1993)). If a claim is unripe, a federal court lacks subject matter jurisdiction and the claim must be dismissed. *Nationwide Mut. Ins. Co. v. Cisneros*, 52 F.3d 1351, 1361 (6th Cir. 1995). The United States Supreme Court outlined the ripeness doctrine in *Abbott Labs. v. Gardner*, 387 U.S. 136 (1967), and two companion cases, *Toilet Goods Ass'n, Inc. v. Gardner*, 387 U.S. 158 (1967) and

Gardner v. Toilet Goods Ass'n, Inc., 387 U.S. 167 (1967). *Id.* at 1361-62. The Court explained:

> Without undertaking to survey the intricacies of the ripeness doctrine it is fair to say that its basic rationale is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.
>
> The problem is best seen in a twofold aspect, requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.

Abbot Labs., 387 U.S. at 148-49. Further, to be ripe for review, claims must satisfy both the fitness and the hardship components of the inquiry. *Cisneros*, 52 F.3d at 1361 (citing *Franklin Fed. Sav. Bank v. Dir., Office of Thrift Supervision*, 927 F.2d 1332, 1336 (6th Cir. 1991)).

1. Fitness for Judicial Decision

The parties agree that, whether Plaintiff's official capacity claims are fit for judicial resolution turns upon (a) whether the claims raise purely legal questions, and (b) whether the decisions they challenge constitute final agency action. *Toilet Goods Ass'n*, 387 U.S. at 163-64; *Abbot Labs.*, 387 U.S. at 149.

a. Purely legal questions

In considering an issue's fitness for judicial decision, the Court's analysis begins with determining whether the issue is purely legal. *Franklin Fed. Sav. Bank*, 927 F.2d at 1336 ("The Supreme Court began with the fact that the issue before it in that case was purely legal." citing *Abbot Labs*, 387 U.S. at 149). Although Plaintiff has raised many issues in its Amended Complaint, Plaintiff submits that only one of those issues is purely legal, *i.e.*, "whether the FDA's prohibition to the access of Provenge to terminally ill patients violates the Constitution." (Doc. # 43 at 28.) Defendants do not disagree with Plaintiff's contention; however, Defendants correctly point out that Plaintiff raises many issues in its official capacity claims that are not purely legal and instead are fact-intensive.

Consequently, Plaintiff raises one purely legal issue.

b. Final agency action

"Final agency action" is both a critical prerequisite to Article III justiciability, namely ripeness, and a necessary element of a cause of action under the APA. 5 U.S.C. § 704; *Dalton v. Specter*, 511 U.S. 462, 469 (1994). As this Court explains in detail *infra*, the Complete Response Letter does not constitute final agency action. Because the Provenge BLA administrative process is ongoing, the FDA may ultimately approve the application, which would render Plaintiff's claims moot.

Thus, this element of the test for fitness for judicial decision is not met. Consequently, even though Plaintiff raised one purely legal issue, that issue is not fit for judicial decision.

2. Hardship to the Parties of Withholding Court Consideration

The final element considered under ripeness is hardship to the parties in deferring consideration by the courts. *Abbott Labs.*, 387 U.S. at 149. Defendants correctly contend that Plaintiff faces no greater hardship from waiting for a final agency decision before bringing suit than the patients who might potentially benefit from many other biologics or drugs intended to treat life-threatening conditions that are under review by the FDA at any given time. (Doc. # 38 at 18.) Indeed, Congress balanced such hardships against the risks and dangers of using unsafe and ineffective drugs when it set the statutory standards for approval of drugs and biologics. *See, e.g., United States v. Rutherford*, 442 U.S. 544, 552-53 & n.9, 556 (1979) (discussing Congressional intent and legislative history, especially in context of risks borne by terminally ill cancer patients).

The FDA's issuance of the Complete Response Letter, at most, potentially prevents access to an unproven and speculative future benefit. Moreover, immediate consideration of the administrative record by this Court could not speed patients' access to Provenge, because the only remedy that this Court could issue is a remand to the FDA to continue its review of Dendreon's BLA. *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985); (Doc. # 33 at 35-36.)

3. Conclusion Ripeness Test

Plaintiff failed to satisfy either prong of the ripeness test – fitness for judicial resolution and hardship from delaying judicial consideration. Under these circumstances, it is without question that Plaintiff's claims are manifestly unripe leaving this Court with no subject matter jurisdiction to hear Plaintiff's official capacity claims.

B. Finality

Even this Court did not lack subject matter jurisdiction over the official capacity claims because they are unripe, the claims would still be dismissed under the doctrine of finality. The APA permits judicial review of "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. "Final agency action" is a necessary element of a cause of action under the APA. *Id.*; *Dalton v. Specter*, 511 U.S. 462, 469 (1994). Indeed, if an action does "not constitute 'final agency action' as used under the APA, the district court lacks subject matter jurisdiction to evaluate the complaint . . ." *Invention Submission Corp. v. Rogan*, 357 F.3d 452, 460 (4th Cir. 2004) (if the action did "not constitute 'final agency action' as used under the APA, the district court did not have subject matter jurisdiction to evaluate the complaint under Rule 12(b)(6) and should have dismissed this case under Rule 12(b)(1)").

As the United States Supreme Court has explained, two conditions must be satisfied for agency action to be final:

> First, the action must mark the 'consummation' of the agency's decisionmaking process–it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which "rights or obligations have been determined" or from which "legal consequences will flow."

Bennett v. Spear, 520 U.S. 154, 177-78 (1997) (citations omitted). *See also Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992) ("The core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties."). In addition, the action must not be that of a subordinate official. *Franklin*, 505 U.S. at 797 (internal quotation marks omitted; quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 151 (1967)); *Air Brake Sys. v. Mineta*, 357 F.3d 632, 640 (6th Cir. 2004) (quoting same passage from *Abbott Labs.*). None of these conditions is satisfied in the instant action.

The agency action at issue here is the issuance of the Complete Response Letter. Although Plaintiff acknowledges that it must show that the agency action is final, Plaintiff sets forth an entire two pages of factual assertions–including direct quotes–without so much as one citation to the evidentiary source of the assertions. (Doc. # 43 at 15-17.) However, even if this Court were to accept Plaintiff's factual assertions, Plaintiff has utterly failed to apply the applicable law

to those facts. Indeed, as Defendants correctly state: "The total of [Plaintiff's] analysis on final agency action is the conclusory assertion that any 'argument' that 'there has been not final decision made . . . lacks any merit what so ever and is close to laughable." (Doc. # 47 at 4-5 citing Doc. # 43 at 17.) Plaintiff's conclusory statement falls far short of supporting Plaintiff's claim that the issuance of the Complete Response Letter constitutes final agency action.

In glaring contrast, Defendants have convincingly shown that issuance of a Complete Response Letter does not constitute final agency action. (Doc. # 38 at 12-19; Doc. # 47 at 1-7.) A Complete Response Letter is an established mechanism for the FDA to request additional information from the sponsor of a BLA. FDA, *Applications for Approval to Market a New Drug*, 69 Fed. Reg. 43351, 43352 (July 20, 2004). A Complete Response Letter is meant to "ensure a consistent approach to informing sponsors of needed changes before [the FDA] can approve an application, with no implication as to the ultimate approvability of the application." *Id.* A Complete Response Letter does not signal the end for a product; rather, it is a step the FDA takes to assure that it has sufficient data to establish safety and effectiveness prior to licensure. The FDA continues to work with sponsors to resolve any outstanding issues. *See id.*

Indeed, the Complete Response Letter made clear that it was not "the consummation of the agency's decisionmaking process" and instead was an interlocutory step in the agency's administrative process. *See Dendreon Receives Complete Response Letter.* The letter affirmatively requests Dendreon to

submit additional evidence to support its BLA. *See id.* ("The FDA has requested additional clinical data in support of the efficacy claim contained in the BLA."). In its press release, Dendreon explained that "[w]e are committed to working closely with the FDA to resolve these questions in a timely and efficient manner." *Id.* Thus, Dendreon clearly understood the letter to be "of a merely . . . interlocutory nature." *Bennett*, 520 U.S. at 178. Because the Provenge BLA administrative process is ongoing, the FDA may ultimately approve the application, which would render Plaintiff's claims moot. Under these circumstances, the challenged FDA action is clearly not a "final agency action" as that phrase is interpreted under the APA. 5 U.S.C. § 704. *See also Telespectrum, Inc. v. Pub. Serv. Comm'n of Ky.*, 227 F.3d 414, 423 (6th Cir. 2000) (the agency's order "contain[ed] no language which indicates that PSC will hear further evidence").

In addition, the Complete Response Letter did not determine any legal rights or obligations, or trigger a process "from which legal consequences will flow." *Bennett*, 520 U.S. at178 (internal quotation marks and citations omitted). To be sure, makers of biologic products cannot market them without an approved BLA. 42 U.S.C. § 262(a). But the Complete Response Letter neither approved, nor denied, Dendreon's BLA. It thus did not "alter the legal regime" and "in no way affected the legal rights of the relevant actors." *Bennett*, 520 U.S. at 178.

Finally, the Complete Response Letter was the ruling of a subordinate official. It was signed by Dr. Ashok Batra, who is the Director of the Division of Clinical Evaluation and Pharmacology/Toxicology

within the Office of Cellular, Tissue, and Gene Therapies, which is in turn within CBER. CBER has delegated to officials at Dr. Batra's level the authority to issue Complete Response Letters, but not the authority to approve BLAs. CBER, "*Signature Authority for Action Letters*," Sept. 20, 2004, in Manual of Standard Operating Procedures and Policies, SOPP 8405, ver. 4, App. 1, available at http://www.fda.gov/cber/regsopp/8405sign.htm. In *Air Brake Systems*, the Sixth Circuit found that actions taken by subordinate officials did not constitute "final agency action": "While [the agency]'s Chief Counsel has considerable authority over purely legal interpretations of pertinent statutes and regulations, the Secretary has not delegated authority to the Chief Counsel to make final fact-bound determinations of compliance with [the agency]'s safety standards." *Air Brake Sys.*, 357 F.3d at 640. Because the FDA's Complete Response Letter was "only the ruling of a subordinate official," *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992), to whom the Commissioner has not delegated authority to approve BLAs, it was not a final agency action. *See also Air Brake Sys.*, 357 F.3d at 640.

Accordingly, because the Complete Response Letter does not constitute final agency action under the APA, this Court lacks subject matter jurisdiction over this action and must dismiss it.

C. Sovereign Immunity

Even if the official capacity claims did not lack subject matter jurisdiction based upon the doctrines of finality and ripeness, it would still be dismissed based upon the doctrine of sovereign immunity. "Jurisdiction

over any suit against the [United States] Government[2] requires a clear statement from the United States waiving sovereign immunity . . . together with a claim falling within the terms of the waiver." *United States v. White Mountain Apache Tribe*, 537 U.S. 465, 472 (2003). Indeed, it is "axiomatic that the United States may not be sued without its consent and that the existence of consent is a prerequisite for jurisdiction." *United States v. Mitchell*, 463 U.S. 206, 212 (1983); *see also Reed v. Reno*, 146 F.3d 392, 398 (6th Cir. 1998) ("The United States can be sued only when it has expressly given its consent to be sued.") (internal quotation marks and citation omitted).

Waivers of sovereign immunity "cannot be implied but must be unequivocally expressed." *Mitchell*, 463 U.S. at 239; *Reed*, 146 F.3d at 398 (waiver must be "express, clear and unequivocal"). Thus, absent an express waiver of sovereign immunity, a district court lacks jurisdiction over claims against the United States. *See, e.g., Mitchell*, 463 U.S. at 212. It is Plaintiff's burden to "identify a waiver of sovereign immunity in order to proceed against the United States. If [it] cannot identify a waiver, the claim must

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[2] The FDA is part of the Department of Health and Human Services, 21 U.S.C. § 393(a), which Congress has established as one of the fourteen Executive Branch departments, 5 U.S.C. § 101. Sovereign immunity is thus fully applicable to actions brought against the FDA and/or its officials. *See, e.g., NVE Inc. v. HHS*, 436 F.3d 182, 189 (3d Cir. 2006) (holding that challenge to FDA regulation banning dietary supplements containing ephedra must proceed under APA because Dietary Supplement Health and Education Act did not provide a private cause of action or "contain a waiver of sovereign immunity that would permit [plaintiff] to sue a federal agency").

be dismissed on jurisdictional grounds." *Reetz v. United States*, 224 F.3d 794, 795 (6th Cir. 2000).

In the case *sub judice*, Plaintiff argues that "[t]here is no immunity for intentional conduct done with malice that rises to the level of a constitutional tort" and thus asserts that "[n]either the government itself nor the government officials Dr. von Eschenbach, Dr. Scher, and Dr. Pazdur have immunity from being sued." (Doc. # 43 at 80.) This argument, however, as Defendants correctly note, confuses sovereign immunity with the concept of qualified immunity that is applicable only to Plaintiff's claims against Pazdur and Scher in their individual capacity. Plaintiff's reliance on caselaw concerning the standards for imposing individual liability on government officials is thus misplaced. *Id.* at 80-82.

Plaintiff's next argument centers on a series of United States Supreme Court decisions from the 1930s and 1940s that dealt with government-chartered corporations authorized to conduct financial business transactions and to "sue and be sued" in their own name. *Id.* at 81 (citing *Keifer & Keifer v. Reconstruction Fin. Corp.*, 306 U.S. 381 (1939) (Reconstruction Finance Corp.); *FHA v. Burr*, 309 U.S. 242 (1940) (Federal Housing Administration); *Reconstruction Fin. Corp. v. Menihan Corp.*, 312 U.S. 81 (1941) (Reconstruction Finance Corp); and *Standard Oil Div. v. Starks*, 528 F.2d 201 (7th Cir. 1975) (United States Postal Service)). The rulings in those cases were based on findings that Congress had not meant to endow such entities with sovereign immunity. Plaintiff here appears to rely on these cases for support of its contention that the FDA

likewise lacks immunity from suit. Plaintiff's reliance, however, is misplaced.

Even assuming these decisions are still good law, the FDA is not a quasi-governmental business entity or private corporation like the Reconstruction Finance Corporation or the Postal Service, nor can it sue and be sued in its own name. *See Parrett v. Se. Boll Weevil Eradication Found., Inc.*, 155 Fed. Appx. 188, 191 (6th Cir. 2005) (questioning continued authority of *Keifer* and its progeny); *Galvan v. Fed. Prison Indus., Inc.*, 199 F.3d 461, 467 (D.C. Cir. 1999) (same). Rather, the agency is part of the Department of Health and Human Services, 21 U.S.C. § 393(a), which Congress has established as one of the fourteen Executive Branch departments, 5 U.S.C. § 101. Sovereign immunity is thus fully applicable to actions brought against the FDA and/or its officials. *See, e.g., NVE Inc. v. HHS*, 436 F.3d 182, 189 (3d Cir. 2006) (holding that challenge to FDA regulation banning dietary supplements containing ephedra must proceed under APA because Dietary Supplement Health and Education Act did not provide a private cause of action or "contain a waiver of sovereign immunity that would permit [plaintiff] to sue a federal agency").

Plaintiff next argues that this Court should "exercise its power of equity jurisdiction," by which Plaintiff presumably means the Court's power to enter injunctive or other equitable relief where a plaintiff has no adequate legal remedy. (Doc. # 43 at 82-83.) Although it is unclear whether Plaintiff asserts this argument as a means to avoid the bar of sovereign immunity or for some other purpose, it goes without saying that a court's exercise of equitable authority

depends in the first instance on the existence of subject matter jurisdiction. *See Mickler v. Nimishillen & Tuscarawas Ry. Co.*, 13 F.3d 184, 189 (6th Cir. 1993); *see also Wooten v. United States*, 825 F.2d 1039, 1045 (6th Cir. 1987) ("Since federal courts are courts of limited jurisdiction, jurisdiction that is otherwise lacking cannot be conferred by [equitable doctrines such as] consent, collusion, laches, waiver, or estoppel.").

For the same reason, *i.e.*, lack of subject matter jurisdiction, Plaintiff's reference to declaratory relief under Rule 57 of the Federal Rules of Civil Procedure is equally unavailing. (Doc. # 43 at 85.) The Declaratory Judgment Act, 28 U.S.C. § 2201, does not waive sovereign immunity or create an independent basis for jurisdiction, but merely provides courts with the discretion to fashion a remedy. *See Heydon v. MediaOne of Se. Mich., Inc.*, 327 F.3d 466, 470 (6th Cir. 2003). Thus, declaratory relief, like injunctive relief, is only available if the court otherwise has subject matter jurisdiction over the action.

Finally, Plaintiff turns to the APA,[3] observing correctly that, although the APA does not itself confer subject matter jurisdiction, it does waive sovereign immunity for certain nonmonetary claims against the United States. (Doc. # 43 at 84); 5 U.S.C. §§ 702, 704.

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[3] In the Amended Complaint, Plaintiff relies on a number of other sources for subject matter jurisdiction. In Defendants' Motion to Dismiss, however, Defendants correctly explain that none of the named sources waives the sovereign immunity to which Defendants are entitled. (Doc. # 38 at 30-34.) Plaintiff, appropriately, does not dispute Defendants' conclusions.

However, by its terms, the APA authorizes challenges only to "final agency action for which there is no other adequate remedy in court." *Beamon v. Brown*, 125 F.3d 965, 967 (6th Cir. 1997) ("Although the APA provides a broad waiver of sovereign immunity, codified at 5 U.S.C. § 702, the waiver is limited . . . . [U]nder the APA, a federal district court may only review '[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court.' "). Such statutory waivers of sovereign immunity are "strictly construed in favor of the United States." *Reed*, 146 F.3d at 398.

In the instant action, this Court has already concluded that a Complete Response Letter is in no sense a "final agency action." Consequently, Plaintiff has not stated a claim under the APA, which prevents it from availing itself to the APA's waiver of sovereign immunity. Because Plaintiff has failed to identify any waiver of sovereign immunity applicable to its claims, its complaint must be dismissed for lack of subject matter jurisdiction.

V. CONCLUSION

This Court lacks subject matter jurisdiction over the official capacity claims brought against Defendants based on the doctrines of ripeness, finality, and sovereign immunity. Therefore, the Court **GRANTS** Defendants' Motion to Dismiss Plaintiff's Official Capacity Claims (Doc. # 38) and **GRANTS** Defendants' Motion to Strike Improper Supplemental Memorandum (Doc. # 59).

IT IS SO ORDERED.

/s/ Gregory L. Frost
GREGORY L. FROST
UNITED STATES DISTRICT JUDGE

APPENDIX C

5 U.S.C. § 702

United States Code Annotated Currentness
Title 5. Government Organization and Employees (Refs & Annos)
Part I. The Agencies Generally
Chapter 7. Judicial Review (Refs & Annos)

5 U.S.C. § 702. Right of review

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party. The United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: *Provided*, That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance. Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any

other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.

CREDIT(S)

(Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 392; Pub.L. 94-574, § 1, Oct. 21, 1976, 90 Stat. 2721.)

5 U.S.C. § 704

United States Code Annotated Currentness
Title 5. Government Organization and Employees (Refs & Annos)
Part I. The Agencies Generally
Chapter 7. Judicial Review (Refs & Annos)

5 U.S.C. § 704. Actions reviewable

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.